UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BRUCE SCHULTZ, Individually and On Behalf of All Others Similarly Situated, Plaintiff, vs. EISAI CO., LTD and EISAI INC., Defendants.	No. 07-cv-1985-GEL **"ECF CASE"** CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE CARTWRIGHT ACT AND UNFAIR COMPETITION ACT **JURY TRIAL DEMANDED**

Plaintiff Bruce Schultz, upon information and belief, brings this Class Action Complaint against defendants Eisai Co., Ltd. and Eisai Inc. (collectively "Eisai" or "Defendants") on behalf of himself and the class he represents, for treble damages, restitution, and injunctive relief. Plaintiff respectfully alleges as follows:

NATURE OF THE ACTION

1. This is a class action brought on behalf of California residents under the antitrust and deceptive practices statutes of the state of California to remedy anticompetitive actions by Defendants to delay and prevent generic competition for prescription drugs composed of delayed-release rabeprazole sodium.

2. Eisai sells delayed-release rabeprazole sodium in the United States under the brand name Aciphex. Aciphex is a widely prescribed proton pump inhibitor that suppresses acid production in the cells of the stomach lining. Aciphex was approved by the U.S. Food & Drug Administration ("FDA") in 1999 for the healing of erosive gastroesophageal reflux disease ("GERD"), maintenance of healed erosive GERD, healing of

duodenal ulcers, and treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome. It is also approved for treatment of daytime and nighttime heartburn and other symptoms associated with GERD. Aciphex is sold by Eisai as delayed-release, enteric-coated tablets in a 20mg dose.

3. Defendants have engaged in unlawful and anti-competitive conduct designed to create and preserve a monopoly over the market for Aciphex and its generic bioequivalents.

4. The anticompetitive acts of Defendants involve fraud and inequitable conduct in obtaining U.S. Patent No. 5,045,552 (the "552 patent") through an intentional failure to disclose known prior art to the Patent and Trademark Office ("PTO"). This misconduct also involved, among other things, the intentional suppression of material information about the patentability of the '552 patent from the patent examiner.

5. Several generic pharmaceutical manufacturers, including Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "Reddy"); Teva Pharmaceuticals USA, Inc. ("Teva"); and Mylan Laboratories, Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan") have filed applications requesting FDA approval to market generic versions of Aciphex. In their applications to the FDA, these manufacturers have asserted that, among other things, their products are bioequivalent to Aciphex and the '552 patent is invalid.

6. In response, Defendants initiated a series of baseless patent infringement litigation against Reddy, Teva, and Mylan, even though Eisai knew that the '552 patent was improperly procured and that no reasonable claim of infringement could be based upon it.

7. Eisai filed these lawsuits, not for any legitimate purpose, but because it knew that the mere filing of such litigation would raise barriers to the entry of generic competition, including automatically delaying the FDA's granting of final marketing approval to the generic manufacturers. Without such approval, generic manufacturers cannot bring their products to market.

8. By its unlawful acts, Eisai has willfully and unlawfully maintained its monopoly power over Aciphex and generic, bioequivalent forms of the drug, *i.e.*, the delayed-release rabeprazole sodium "molecule."

9. Eisai's anticompetitive scheme has been extraordinarily successful in protecting its revenues from Aciphex, which amount in the United States to over $1 billion annually. Because of Eisai's scheme, no generic competitor has been able to sell a generic version of Aciphex.

10. This class action is brought on behalf of all indirect purchasers in the state of California (*i.e.*, consumers and other persons or entities that pay for prescriptions for family members, employees or insureds) who purchased or paid for Aciphex since January 17, 2006 (see Class Definition ¶ 19).

JURISDICTION AND VENUE

11. This Complaint alleges violations of California law on behalf of the consumers of the State of California, arising under California Bus. & Prof. Code §§16700 et seq. (the "Cartwright Act") and California Bus. & Prof. Code §§17200 et seq. (the "Unfair Competition Act").

12. This Court has subject matter jurisdiction over this case under 280 U.S.C. §1332 as there is complete diversity between Plaintiff and the class he seeks to represent

and Defendants. In addition, this Court has subject matter jurisdiction pursuant to the Class Action Fairness Act of 2005 ("CAFA"), 28 U.S.C. §1711 et seq., and 28 U.S.C. §1332(d)(2) as the aggregate amount in controversy exceeds $5,000,000 and the citizenship of Plaintiff is different from the citizenship of Defendant Esai.

13. Venue is proper in this District under 15 U.S.C §15(a), 22, and 26, and under 28 U.S.C. §1391, because Defendants transact business, committed an illegal tortuous act, have an agent, and/or are found within this District, and/or a substantial portion of the events described below have been carried out in this District.

PARTIES

Plaintiff

14. Plaintiff Bruce Schultz is a resident of California. During the relevant time period, Plaintiff indirectly purchased Aciphex at supra-competitive prices for his personal treatment and not for resale.

Defendants

15. Defendant Eisai Co., Ltd., a Japanese company based in Tokyo, is involved in the manufacture and marketing of pharmaceutical drugs, over-the-counter drugs, and pharmaceutical production systems and equipment. Eisai Co. Ltd.'s headquarters are located at 4-6-10 Koishikawa, Bunkyo-ku, Tokyo, 112-8088, Japan. The company sells Aciphex – known as Pariet outside of the United States – throughout the world, including in the United States.

16. Defendant Eisai Inc., the U.S. Pharmaceutical subsidiary of Eisai Co., Ltd., was established in 1995. Eisai Inc. has sales of nearly $2.2 billion in fiscal year 2005 (year ending March 31, 2005). Eisai Inc. is incorporated under the laws of the State

of Delaware, with its headquarters at Glenpointe Centre West, 5th Floor, 500 Frank W. Burr Boulevard, Teaneck, New Jersey, 07666-6804. Eisai Inc. also has a pharmaceutical production and formulation research and development facility in Research Triangle Park, North Carolina, which manufactures and packages Aciphex. Eisai Inc. distributes Aciphex in the United States; it co-promotes the drug with PriCara, Unit of Ortho-McNeil, Inc. As noted, Eisai Co., Ltd. and Eisai Inc. are collectively referred to herein as "Eisai."

17. The acts charged in this Complaint as having been performed by Eisai were authorized, ordered, or performed by its officers, agents, employees or representatives, while actively engaged in the management of the Defendant's businesses or affairs.

RELEVANT MARKET

18. The relevant product market is the market for the manufacture and sale of prescription drugs composed of delayed-release rabeprazole sodium, including Aciphex, and any and all generic bioequivalents rated "AB" by the FDA. The relevant geographic market is the United States and its territories as a whole.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

19. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of the class, which consists of:

> All persons or entities in the state of California who purchased, paid for and/or reimbursed for prescription drugs composed of delayed-release rabeprazole sodium, including Aciphex, in California for consumption by themselves, their families or their members, employees or insureds during the period January 17, 2006, through such time in the future as the effects of Defendants' illegal conduct, as alleged herein, has ceased (the "Class Period"). Excluded from the Class are Defendants and their respective subsidiaries and affiliates, governmental entities and all persons or entities that purchased prescription drugs composed of delayed-release rabeprazole sodium (i) for purposes of resale,

or (ii) directly from any of the Defendants or their affiliates (the "Class").

20. While the exact number of Class members is unknown to Plaintiff and can only be ascertained through appropriate discovery, Plaintiff believes that there are thousands of members of the Class. Purchasers of Aciphex in the State of California may be notified of the pendency of this action by mail or publication, using the form of notice similar to that customarily used in class actions.

21. Plaintiff's claims are typical of the Class because they and all members of the Class were injured and continue to be injured in the same manner by Defendants' unlawful, anti-competitive, fraudulent and inequitable methods, acts and practices, and wrongful conduct in the conspiracies complained of herein, *i.e.*, they have paid supra-competitive and artificially high prices for Aciphex and will continue to be forced to do so until the markets for Aciphex and its generic equivalents are competitive and prices have stabilized to competitive levels.

22. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class action litigation.

23. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since joinder of all Class members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for the Class members to seek redress individually for the wrongs done to them. There will be no difficulty in the management of this action as a class action.

24. Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting solely individual members of the Class. Among the questions of law and fact common to the Class are:

(a) Whether Defendants have unlawfully monopolized or attempted to monopolize the market for Aciphex and its generic equivalents;

(b) Whether Defendants possessed and/or unlawfully extended their monopoly power over the market for Aciphex and its generic equivalents;

(c) Whether Defendants have fixed, raised, maintained or stabilized the prices of Aciphex at supra-competitive and artificially high prices;

(d) Whether Defendants engaged in fraud or inequitable conduct before the PTO in obtaining the '552 patent; and

(e) Whether Defendants were and continue to be unjustly enriched to the detriment of the Class, entitling Plaintiffs and the Class to disgorgement of all monies resulting therefrom.

25. Defendants have acted or refused to act, as alleged herein, on grounds generally applicable to the Class, thereby making appropriate final injunctive relief and/or corresponding declaratory relief with respect to the Class as a whole.

BACKGROUND

The Federal Scheme for Approval of Pioneer Drugs

26. Under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq*. (the "Act"), approval by the FDA is required before a company may begin selling a new drug. Pre-market approval for a new drug, often referred to as a "pioneer" or "branded" drug, must be sought by filing a New Drug Application ("NDA") with the FDA demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are often (but not necessarily) covered by

patents, which provide the patent owner with the exclusive right to sell that new or pioneer drug in the United States for the duration of the patents involved, plus any extension of the original patent period (the "FDA Exclusivity Period") granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 ("Hatch-Waxman Act").

27. In addition to information on safety and efficacy, NDA applicants must submit to FDA a list of all patents that claim the drug for which FDA approval is being sought, or that claim a method of using the drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug. When the NDA is approved, the FDA "shall publish" the patent information submitted by the NDA applicant 21 U.S.C. §355(b)(1).

28. Once the NDA is approved, the FDA lists any patent referenced as part of the NDA application process in a publication known as "Approved Drug Products With Therapeutic Equivalence Evaluations" – commonly called the "Orange Book."

29. Pursuant to 21 U.S.C. § 355(c)(2), if, after its NDA is approved, the pioneer drug manufacturer obtains a new patent that claims the drug or methods of its use, the company must supplement its NDA by submitting information on the new patent within 30 days of issuance. The FDA then lists the new patent in a supplement to the Orange Book. The FDA is required to accept as true the patent information it obtains from patent holders and to withhold its approval of a subsequent drug application whenever the patent holder presents a litigated dispute (baseless or not) concerning the validity of infringement of the patent. If an unscrupulous patent holder provides false information to

the FDA, or files frivolous patent infringement actions to delay the onset of generic competition, the FDA is powerless to stop it.

30. Once the FDA approves the new drug as safe and effective, it may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be dispensed by a licensed pharmacist. The pharmacist must, in turn, fill the prescription with the drug brand specified by the physician, unless an AB-rated generic version of the pioneer drug which has been approved by the FDA is available.

Generic Drugs

31. A generic drug is a drug which the FDA has found to be bio-equivalent to the listed and named drug. Where a generic drug is bio-equivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating.

32. If a generic version of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing the branded drug or the AB-rated generic (at a lower price).

33. When a physician writes a prescription for a brand-name drug such as Aciphex, that prescription defines and limits the market to the drug named or its AB-rated generic equivalent. Only drugs that carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug.

34. Generic drugs invariably are priced below the branded drugs for which they are bioequivalent. A branded drug loses a significant portion of its market share to generic competitors less than one year after the introduction of generic competition, unless the branded manufacturer lowers its prices to meet competition.

Abbreviated New Drug Applications For Generic Drugs

35. Congress enacted the Hatch-Waxman Act in 1984 to establish an abbreviated process to expedite and facilitate the development and approval of generic drugs. Consumers benefit from the choice and competition. To effectuate this purpose, the Hatch-Waxman Act permits a generic drug manufacturer to file an "abbreviated" new drug application ("ANDA"), which incorporates by reference the safety and effectiveness data developed and previously submitted by the company that manufactured the original "pioneer" drug. The Act also provides an economic incentive to the manufacturer of the first generic drug to file an ANDA for a particular generic drug – a 180-day statutory period of market exclusivity, during which time the generic manufacturer has the right to market its drug free from other generic competition.

36. Information that must be included in the ANDA concerns the generic manufacturer's position *vis-à-vis* the patent that the pioneer manufacturer claims applies to the drug. The ANDA filer must make one of four certifications:

> That no patent for the pioneer drug has been filed with the FDA (a "Paragraph I Certification");
>
> That the patent for the pioneer drug has expired (a "Paragraph II Certification");
>
> That the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or

> That the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii). In the case of a patent that has not yet expired, the ANDA applicant's only certification options are Paragraph III or IV certifications. *See id*.

37. If the ANDA contains a Paragraph IV Certification, the ANDA applicant must provide notice to the owner of each patent that is referred to in the certification and to the holder of the approved NDA to which the ANDA refers. *See id;* 21 C.F.R. § 314.95.

38. The first filer of an ANDA with a Paragraph IV Certification is eligible for the 180-day statutory period of market exclusivity during which it can market its generic version free from other generic competition. The 180-day exclusivity period is triggered by either: (a) commercial marketing of the generic product; or (b) a final court decision that the patent at issue is either invalid or not infringed.

39. Upon receiving a Paragraph IV Certification from an ANDA applicant, the branded-drug patent owner has 45 days to initiate a patent infringement suit against the applicant. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If no action is initiated within 45 days, FDA approval of the generic product is not delayed by patent issues. However, if a patent infringement suit is brought within the 45-day window, the FDA approval of the ANDA is automatically postponed until the earliest of the expiration of the 30 months from the patent holder's receipt of notice of Paragraph IV Certification, or a final judicial determination of a non-infringement of all patents. Prior to the expiration of the 30-month stay of FDA approval, the FDA may grant "tentative" approval of an ANDA once it determines that all the criteria for "final" approval have been satisfied.

40. The FDA has stated that it does not evaluate the merits of a patent claim, but merely acts in a ministerial role, initiating the stay provision automatically if a patent suit is filed. Thus, branded drug patent holders need only file a patent infringement law-suit within 45 days of receipt of a Paragraph IV Certification in order to automatically block an ANDA applicant's generic drug from entering the market for up to 30 months.

EISAI'S ANTICOMPETITIVE CONDUCT

41. Eisai has successfully forestalled generic competition to Aciphex from entering the market – thereby depriving purchasers of the benefits of cheaper delayed-release rabeprazole sodium products – by improperly procuring the '552 patent through misconduct before the PTO, listing the '552 patent in the Orange Book, and bringing and maintaining a series of sham patent infringement suits based on this patent.

Eisai's Misconduct Before the PTO

1. Eisai's procurement of the '552 patent

42. Eisai has asserted that the '552 patent covers Aciphex and bars generic competition. The '552 patent claims, among other things, the chemical compound rabeprazole and its salts.

43. On November 10, 1987, Eisai's attorney Arthur R. Crawford filed the application that resulted in the '552 patent. The application reported that the compound now referred to as rabeprazole belonged to a known class of chemical structures that include a benzimidazole ring on the left side of the molecule as diagramed in the standard chemical notation, and a pyridine ring on the right, joined by a sulfinylmethyl group.

44. Numerous compounds feature this basic chemical structure, including omeprazole, a different proton pump inhibitor, first disclosed in a group of patents

(known as "Junggren" after an inventor) owned by the Swedish company now known as AstraZeneca AB. Compounds that share this basic chemical structure may differ by the particular "substitutions" of chemical groups for hydrogen atoms around their pyridine rings. The structure of rabeprazole's pyridine ring reflects a patterns of substitution referred to as "asymmetrical," because its 3-position is substituted (with a methyl group) while the 5-position is unsubstituted (*i.e.* bonded to a hydrogen atom). The 4-position is substituted with a methoxypropoxy group, a type of alkoxy group. Other related compounds, some of which are potentially useful in the inhibition of gastric-acid formation, have different patterns of pyridine-ring substitution, including the use of different alkoxy groups at the 4-position.

45. Eisai reported that it synthesized rabeprazole by working from omeprazole. Eisai disclosed three sets of pharmacological data that purported to demonstrate rabeprazole's superior potency and its enabling of faster post-dosage recovery of acid secretion.

46. PTO patent examiner Jane Fan rejected Eisai's rabeprazole claims three times, prompting various persuasive efforts by Eisai, before ultimately allowing the claims to issue as the '552 patent.

47. On September 21, 1988, examiner Fan issued her first rejection, stating that the claims were obvious in light of certain prior art: the Junggren patents and Great Britain Patent No. 2,234,532 ("GB '523"), which both teach compounds with the 4-position on the pyridine ring being methoxyethoxy or ethoxyethoxy. Examiner Fan concluded that the prior art compounds are homologs of the claimed compounds, rendering the claimed compounds unpatentable.

48. On March 21, 1989, Eisai responded through attorney Crawford by purporting to address both the structural and functional distinctiveness of rabeprazole. With respect to chemical structure, Eisai attempted to distinguish rabeprazole's 4-position substituent, methoxypropoxy, from those of compounds in the prior art. Eisai also asserted the distinctiveness of rabeprazole's asymmetrical substitution pattern. With respect to functionality, Eisai asserted that compounds "in which the substituent at the 4-position is propoxymethoxy" exhibited "unexpected anti-ulcer activity." It also submitted additional pharmacological comparisons with omeprazole, alleging omeprazole's overall inferiority with respect to acid-inhibition and post-dosage recovery. Eisai attempted to justify its choice of omeprazole as a basis for comparison, even though other compounds were more closely related structurally.

49. In a May 4, 1989, "Supplemental Response," Eisai offered still further omeprazole-related arguments in favor of its claimed compound's superiority. Again, Eisai explained its choice of omeprazole as a comparator, this time arguing it was selected because it was the "most interesting" related compound.

50. Patent examiner Fan issued her second rejection of the rabeprazole claims on July 14, 1989. Among other things, Fan rejected Eisai's reasoning in submitting comparison data for omeprazole rather than for a structurally closer prior-art compound.

51. Attorney Crawford spoke with Fan on August 3, 1989, following this second rejection. On December 28, 1989, Crawford filed a continuation of the rabeprazole application, to avoid expiration of the claims.

52. On July 17, 1990, Fan issued her third rejection of the rabeprazole application, reiterating reasons from her prior rejections. Fan again rejected Eisai's rationale for

comparing only omeprazole, adding that the "closest prior art compounds should be compared with the claimed compounds."

53. In response, on January 11, 1991, Eisai both narrowed its claims, limiting them to only those relating to rabeprazole, and attempted to strengthen its case for patentability. Eisai submitted a declaration by named inventor and Eisai employee Hideaki Fujisaki (the "Fujisaki Declaration"), purporting to show rabeprazole's superior performance in an *in vitro* acid-inhibition test comparing the ability of three compounds, including one from the Junggren patents, to inhibit the secretion of gastric acid. None of the three compared compounds share rabeprazole's asymmetrical pyridine-ring substitution pattern. But Eisai did not mention the asymmetry feature as distinguishing rabeprazole from the compared compounds, instead it stressed rabeprazole's particular 4-position substituent (*i.e.* methoxypropoxy).

54. On April 3, 1991, Fan allowed the rabeprazole application to issue as the '552 patent.

2. Eisai's prosecution of a co-pending patent application

55. On June 16, 1988, approximately seven months after filing the application for the '552 patent, Eisai attorney Crawford filed an application that would ultimately issue as U.S. Patent No. 5,708,013 (the "'013 patent"). The application for the '013 patent listed the same fourteen inventors as the '552 patent application and claimed a compound similar to rabeprazole in structure, prior art, and asserted properties. Eisai had even written into its rabeprazole application a limitation purporting to exclude certain similar compounds – including the compound covered by the '013 application – from being considered part of the '552 application.

56. Eisai prosecuted the two patent applications separately before different patent examiners and, during some three years' overlap in the pendency of the two prosecutions, did not disclose in either one the existence of, or any occurrences in, the other.

57. The structure of the compound claimed in the '013 application differs from rabeprazole's by a single methylene unit at the 4-position of the pyridine ring, where it bears a methoxyethoxy substituent, while rabeprazole bears a methoxypropoxy. (This compound will be referred to as the "ethyl homolog" of rabeprazole, after the ethyl segment that differs from rabeprazole's propyl segment.) The two compounds are otherwise structurally identical.

58. On April 21, 1989, the PTO rejected the ethyl homolog claim (claim 8) of the application that issued as the '013 patent for lack of novelty, as anticipated by the Junggren prior art reference. The PTO also rejected claims in the application that would issue as the '013 patent other than the ethyl homolog for being obvious in light of a combination of Junggren and either of two prior art references not mentioned in the '552 patent prosecution. One of these two references is referred to as "Byk Gulden."

59. Eisai responded to the PTO's first rejections of the application that would issue as the '013 patent in much the same way as it did to the first rejection of the rabeprazole application, namely by emphasizing the asymmetrical pyridine-ring substitution pattern of Eisai's claimed compounds and asserting superiority to omeprazole in inhibiting gastric acid secretion. Going beyond its rabeprazole argument, however, Eisai also argued omeprazole's lack of asymmetrical substitution.

60. On December 6, 1989, the PTO again issued a rejection. This time, the ethyl homolog claim, along with the others, was specifically rejected under 35 U.S.C.

§ 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Junggren in view of Byk Gulden. Thus, the PTO cited Byk Gulden – a prior art reference never volunteered by Eisai in *either* prosecution – directly regarding the ethyl homolog of rabeprazole.

61. The PTO's December 6, 1998 action also dismissed Eisai's asymmetrical-substitution argument, finding that the prior art actually revealed this feature. The rejection pointed to specific compounds in Byk Gulden that served to make Eisai's claims obvious. The PTO cited yet another combination that rendered the ethyl homolog claims obvious: Byk Gulden combined with another prior art application, Carlsson (which '552 patent examiner Fan had mentioned as a prior art compound to rabeprazole), taught asymmetrical substitution at the 3- and 5-positions and methoxyethoxy substituent at the 4-position. Finally, Eisai's data purporting to demonstrate the pharmacological superiority of the ethyl homolog claims over omeprazole were dismissed as unpersuasive.

62. Eisai tried again on June 6, 1990, with another submission responding to the second rejection. In this submission, Mr. Crawford sought to diminish the import of the prior-art teachings cited by the PTO, arguing that they were "broad" and "generic." Eisai then asserted "evidence of unexpectedly good inhibition of gastric secretion," as it had in the rabeprazole prosecution. Its response, again, emphasized the pyridine-ring substitution pattern. Eisai argued that Junggren and Carlsson did not disclose compounds addressing this pyridine-ring structure. However, Eisai did not address the PTO Byk Gulden findings here, or any point in either prosecution.

63. On August 9, 1990, in a final action, the PTO rejected Eisai's arguments on behalf of the ethyl homolog claims. Squarely countering Eisai's interpretations of

Junggren and Carlsson, Patent Examiner Joseph McKane stated: "The prior art teaches methyl at the 3-position, hydrogen [*i.e.* non-substitution] at the 5-position, and methoxyethoxy at the 4-position."

64. Eisai did not further pursue its claims to the ethyl homolog. Instead, it pressed ahead with the rabeprazole application, which concluded successfully with the issuance of the '552 patent in April, 1991.

Eisai's Filing of Sham Litigation

65. In August of 2003, Reddy and Teva filed ANDAs with the FDA, seeking approval to market generic rabeprazole-sodium products before expiration of Eisai's '552 patent. Reddy and Teva filed Paragraph IV Certifications and provided notice of their certifications to Eisai.

66. On November 17, 2003, Eisai sued Reddy for infringement of the '552 patent in the Southern District of New York.

67. On November 20, 2003, Eisai sued Teva for infringement of the '552 patent in the Southern District of New York.

68. On January 28, 2004, Eisai sued Mylan Laboratories, Inc. and Mylan Pharmaceuticals Inc. (collectively, "Mylan") for infringement of the '552 patent in the Southern District of New York. Mylan had also filed an ANDA with the FDA, and sought approval to market generic rabeprazole-sodium products before expiration of Eisai's '552 patent.

69. Eisai knew, however, that these lawsuits were baseless. Eisai knew that it had committed inequitable conduct in its prosecution of the '552 patent and that it had purposefully withheld material information from the PTO during patent prosecution and

intentionally misrepresented certain material facts. Eisai knew that it had no reasonable expectations of success for the purpose of delaying generic competition.

70. In seeking issuance of the '552 patent, Eisai, like all patent applicants, was required to comply with all applicable rules and standards of patent prosecutions. As patent prosecution in an *ex parte* process, and the PTO's investigative ability is limited in time and resources, patent applicants owe a duty of candor and good faith to the PTO. At the time of the prosecution of the '552 patent, PTO regulations stated that all individuals involved in preparation or prosecution of the patent application "have a duty to disclose to the [Patent and Trademark] Office information they are aware of which is material to the examination of the application. Such information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent."

71. There is no exception to this duty. An applicant is subject to the duty of candor even (indeed, especially) if making the disclosure would derail its prospects for procuring a patent. A breach of this duty constitutes inequitable conduct and renders all claims of even a valid patent unenforceable.

72. At the time it filed its lawsuits against Reddy, Teva, and Mylan, Eisai knew that it had breached its duty of candor to the PTO and that the '552 patent was unenforceable.

73. Eisai knew that it had breached its duty of candor by several acts and omissions, including by intentionally failing to disclose to patent examiner Fan the existence of, and events during, Eisai's co-pending application for rabeprazole's homolog. Information about this co-pending application was material to the '552 patent application

from the moment it was filed; such information became even more significantly material to the '552 application once rejections in the '013 application began to issue.

74. The existence of the co-pending application for the '013 patent was material, among other reasons, because the claims of the two patents were patentably indistinct. For example, the pharmacological data offered in both applications showed the compounds to be functionally, not just structurally, similar. Eisai's own patenting head has testified that the two compounds were related derivatives of rabeprazole. Given the close similarity of the compounds claimed by the two applications, and the prohibition against double-patenting, Eisai knew or should have known it had a duty to disclose the co-pendency of the '013 application in its '552 application.

75. Eisai's failure to disclose the rejections that ensued in the prosecution of the '013 application during prosecution of its rabeprazole claims constituted further misconduct. Given the close similarity between the ethyl homolog and rabeprazole, the issuance of a rejection of one substantially similar claim was *per se* material to the co-pending prosecution of the other.

76. Moreover, the substantive reasons provided in the ethyl homolog's rejections were themselves material to the rabeprazole application. For example, Eisai wrongly failed to disclose the observation – made in two PTO rejections of the ethyl homolog claims while the rabeprazole application was pending – that prior-art compounds from Junggren taught the asymmetrical 3- and 5-position pyridine-ring substitution pattern that Eisai had pointed out to examiner Fan in its response to her first rejection of rabeprazole. This observation was highly material because Eisai had argued for rabepra-

zole's patentability by noting that certain Junggren compounds were symmetrically substituted, in contrast to the claimed compounds.

77. Eisai also failed to disclose to examiner Fan the revelation of the Byk Gulden prior art reference, uncovered by the '013 patent examiner. The PTO cited this reference, which never came up in the '552 patent prosecution, in all three rejections of the '013 patent application. The rejections raising this reference were highly material to the rabeprazole prosecution because they expressed that the prior art taught a combination of two features – asymmetrical pyridine-ring substitution with a 4-position methoxyethoxy substituent – that directly undermined Eisai's arguments about rabeprazole's distinctiveness.

78. The Byk Gulden-based rejections were also highly material because Byk Gulden was a prior-art reference that specifically taught the use of a methoxypropoxy 4-position substituent. Eisai repeatedly highlighted this particular feature of rabeprazole in its submissions to examiner Fan – even asserting that it was a basis for "novelty" – while suppressing the Byk Gulden reference, which undermined this claim.

79. Eisai also engaged in wrongful conduct by submitting a misleading response, the Fujisaki Declaration, in its final bid to secure the '552 patent. In particular, Eisai asserted structural and performance arguments in rabeprazole's favor, while failing to compare the ethyl homolog to the claimed compound and thereby omitting contradictory information about the ethyl homolog and Byk Gulden. Certain test data relating to the ethyl homolog would have undermined Eisai's claim based on the Fujisaki Declaration that "the compound of the invention having a methoxy-propoxy at the 4' position of the pyridine ring … exhibits surprisingly unexpected [acid-]inhibitory effects … in com-

parison with closely related compounds." Eisai knew that data concerning the ethyl homolog would undercut its case for rabeprazole, and it intentionally omitted this data from its final submission in the '552 patent prosecution.

80. Eisai also materially misrepresented data it presented to purport to show rabeprazole was more potent than omeprazole. Specifically, Eisai deliberately misrepresented material information from an experiment in dogs (the "histamine dog test"), which it reported to demonstrate rabeprazole's superior potency. The specific comparison selected from the histamine dog test lacked statistical significance, a fact know but not disclosed by the relevant Eisai inventors. Eisai had even received notice of this problem in the form of rejections of a related manuscript it had submitted to a science journal during the '552 patent prosecution.

81. Eisai misrepresented the results of another test in dogs (the "pentagastrin dog test"), which it reported as showing a faster post-dosage recovery of acid secretion for rabeprazole than from omeprazole. Eisai deliberately presented the data from this test in a misleading manner by submitting only data relating to post-dosage recovery while withholding other data showing nearly equivalent potency as between omeprazole and rabeprazole during certain time spans of use.

82. Eisai also wrongly withheld all data from another test (the "pylorus-ligated rat test") that did not merely belie rabeprazole's superiority to omeprazole, but potentially showed omeprazole to be a superior compound.

83. For all of these reasons, Eisai knew when it filed its lawsuits against potential generic competitors that it had no reasonable expectation of success. Nevertheless, the mere filing of these lawsuits accomplished Eisai's goal of forestalling generic

competition. For example, the FDA has determined that the ANDAs of Mylan and Teva are ready for marketing approval. Mylan's ANDA received "tentative approval" from the FDA on January 17, 2006, and Teva received "tentative approval" from the FDA on February 15, 2006. Because of the thirty-month stay triggered under the Hatch-Waxman Act by the filing of the meritless lawsuits, however, neither generic company is eligible to receive "final" approval to come to market.

ANTI-COMPETITIVE EFFECTS

84. The purpose of Defendants' anti-competitive conduct is to obtain and maintain monopoly power in the market for Aciphex and its generic bioequivalents. But for the inequitable conduct that resulted in the issuance of the '552 patent, as alleged herein, a generic version of Aciphex would have launched much sooner than such versions will actually be marketed.

85. Defendants have succeeded in obtaining this unlawful market power during the Class Period. With this monopoly power, Defendants have maintained and stabilized prices for Aciphex at artificially high and supra-competitive levels. Due to Defendants' monopolization, horizontal competitors and potential horizontal competitors are being restrained and denied the opportunity to market competing products, which would be marketed at prices substantially less than the cost of Defendants' Aciphex.

86. According to drugstore.com, the current retail price for bottles of 90 tablets of Aciphex is $389.97. A comparison of generic prices, which are generally 30% to 80% lower than branded prices, is not available because no generic versions of Aciphex were on the market as of the date of this Complaint.

87. As a result of Defendants' anti-competitive conduct, Plaintiffs and the Class have been financially injured. First, Plaintiffs and the Class have never had the opportunity to pay for lower-cost generic versions of Aciphex. Second, while Defendants have maintained their monopoly for Aciphex and its generic equivalents, Plaintiffs and the Class have paid and reimbursed supra-competitive and artificially high prices for Aciphex.

FIRST CLAIM FOR RELIEF
(The Cartwright Act)

88. Plaintiffs incorporate herein by reference the allegations contained in ¶¶1-87 above.

89. Beginning at least as early as January 17, 2006, and continuing to the present, Eisai has engaged in combinations of capital, skill and acts with others with the intent, purpose and effect of creating and carrying out restrictions in trade and commerce, increasing the price and limiting and reducing the supply of Aciphex, and restraining trade and preventing competition in Aciphex and its generic bioequivalents. Eisai has monopoly power over Aciphex and its generic equivalents and has exercised monopoly power to exclude competition. As such, Eisai has violated California Business and Professions Code §§ 16720 *et seq*.

90. As a direct and proximate result of Eisai's unlawful combinations and contracts to restrain trade and monopolize the relevant markets, members of the Class have suffered injury to their business or property and have been deprived of the benefits of free and fair competition on the merits.

91. Defendants' unlawful conduct is continuing and unless equitable relief is granted, artificially inflated prices for Aciphex will continue unabated and further inquiry

will be suffered by residents of California who purchase Aciphex and are denied the opportunity to purchase cheaper generic equivalents.

SECOND CLAIM FOR RELIEF
(Unfair Competition Act)

92. Plaintiffs incorporate herein by reference the allegations contained in ¶¶1-91 above.

93. Eisai's conduct in engaging in combinations of capital, skill, and acts with others with the intent, purpose and effect of creating and carrying out restrictions in trade and commerce; increasing the price and limiting and reducing the supply of Aciphex; and restraining trade and preventing competition in the relevant markets of Aciphex and its generic bioequivalents, constitutes and was intended to constitute unfair competition and unlawful and unfair business acts and practices within the meaning of California Business and Professions Code §§ 17200 *et seq.*

94. As a result of Eisai's violations of Business and Professions Code § 17200, Eisai has unjustly enriched itself at the expense of the Class members identified herein. Eisai's unjust enrichment continues to accrue as it continues to engage in its unfair competition and its unlawful business acts and practices.

95. To prevent its unjust enrichment, Eisai should be required pursuant to Business and Professions Code §§17203 and 17204 to disgorge its illegal gains for the purpose of making full restitution to all injured Class members identified herein. Eisai should also be permanently enjoined from continuing its violations of Business and Professions Code §17200.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and the other members of the Class, prays for judgment as follows:

(i) Declaring this action to be a proper plaintiff class action pursuant to Fed. R. Civ. P. 23 and declaring Plaintiff to be a proper representative of the Class;

(ii) Declaring that Eisai has engaged in combinations of capital, skill and acts with others constituting a trust for the purpose of creating or carrying out restrictions in trade or commerce, limiting and reducing the production and increasing the price of merchandise or a commodity, and preventing competition in manufacturing, making, transportation, sale or purchase of merchandise, products or a commodity, in violation of the Cartwright Act (California Business and Professions Code §§16720 *et seq.*) and unfair competition and unlawful and unfair business acts and practices in violation of the California Unfair Competition Act (California Business and Professions Code §§17200 *et seq.*);

(iii) Awarding judgment against all Defendants, jointly and severally, in an amount to be proven at trial in treble the amount of damages, plus attorneys' fees, costs, and interest as allowable by the law for violations of the Cartwright Act;

(iv) Awarding judgment against all Defendants, jointly and severally, in an amount to be proven at trial in treble the amount of damages, plus attorneys' fees, costs, and interest as allowable by the law for violations of the Unfair Competition Act;

(v) Order Eisai to make full restitution to the Class members who have been and continue to be injured by Eisai's violations of §17200, pursuant to Business and Professions Code §17203 and §17204;

(vi) Awarding Plaintiff the costs and expenses in this action including reasonable attorneys', accountants', and experts' fees; and

(vii) Awarding such other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff hereby requests a trial by jury on all issues triable by jury.

Dated: March 7, 2007

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